

## IN THE SPECIFICATION

Amendments to the drawings have necessitated amendments to the Specification in accordance with 37 CFR §1.121(e). The amendments to the Specification are as follows:

1. Delete the section “**BRIEF DESCRIPTION OF THE DRAWINGS**” on pages 16-19 in its entirety and replace it with the following:

### **BRIEF DESCRIPTION OF THE DRAWINGS**

The present invention will be more clearly understood from the following detailed description of the preferred embodiments of the invention and from the attached drawings, in which:

Fig. 1A shows a flat projection of an expandable spacer, in an un-expanded configuration thereof, in accordance with a preferred embodiment of the invention;

Fig. 1B shows a perspective view of the spacer of Fig. 1A;

Figs. 1CA and 1CB shows both an axial flat projection and a front flat projection of the spacer of Fig. 1A, respectively, in an expanded configuration thereof;

Fig. 1D shows a perspective view of the spacer of Fig. 1A, in an expanded configuration thereof;

Figs. 2A-2D illustrate a process of inserting and expanding a spacer, in accordance with a preferred embodiment of the invention;

Figs. 2E-2G illustrate methods of controlling an expansion of a spacer, in accordance with preferred embodiments of the invention;

Figs. 2H-2J illustrate removable and/or adjustable spacers, in accordance with preferred embodiments of the invention;

Figs. 2K-2L illustrate shaped tips for controlling the expansion of a spacer, in accordance with a preferred embodiment of the invention;

Fig. 2M is a spread layout of a spacer including an expansion limiting wire, in accordance with a preferred embodiment of the invention;

Fig. 2N is a spread layout of a self-bending spacer, in accordance with a preferred embodiment of the invention;

Fig. 2OA-Fig. 2OC illustrates a spacer having an internal end-cap, in accordance with a preferred embodiment of the invention;

Fig. 2P illustrates a spacer having a collapsed axis which is not parallel to an expanded axis of the spacer, in accordance with a preferred embodiment of the invention;

Figs. 3A-3E are axial views of spacers with struts in accordance with preferred embodiments of the invention;

Figs. 3F-3M illustrate one method of providing struts between spikes, in this example struts which ring the spacer at the spike peaks;

Fig. 4A shows a flat projection of a spacer having a square profile when expanded, in an un-expanded configuration, in accordance with a preferred embodiment of the invention;

Figs. 4BA and 4BB shows both an axial flat projection and a front flat projection of the spacer of Fig. 4A, respectively, in an expanded configuration thereof;

Fig. 4C is a perspective view of the spacer of Fig. 4A, in an expanded configuration;

Figs. 4DA and 4DB illustrates a variation of the spacer of Figs. 4A-4C, in which spikes only extend in six transaxial directions and not eight, in accordance with a preferred embodiment of the invention.

Fig. 4E illustrates a spacer configuration in which one spacer is expanded within another spacer;

Figs. 5A-5C illustrates a spacer in which slits are formed on the spacer in a spiral pattern;

Figs. 6A-6V illustrate variants of spikes and/or spike orientations, in accordance with alternative preferred embodiments of the invention;

Figs. 6W and 6X illustrate spikes having portions which twist when the spacer is expanded;

Figs. 6XA-6XC illustrate a flat-top spike in accordance with a preferred embodiment of the invention;

Figs. 6XD-6XH illustrate a flat-top spike in accordance with another preferred embodiment of the invention;

Figs. 6XIA-6XLB illustrate a method of removing portions of a spacer, to achieve a desired spike shape;

Figs. 7A and 7B illustrates protrusions on a spacer portion, in accordance with a preferred embodiment of the invention;

Figs. 8Ai-8B illustrates spacers for which axial shrinkage of the spacer is limited by the design of a tube portion of the spacer, in accordance with preferred embodiments of the invention;

Fig. 9A illustrates an excavating tool, in accordance with a preferred embodiment of the invention;

Fig. 9B illustrates the tool of Fig. 9A, in a bent configuration, in accordance with a preferred embodiment of the invention;

Figs. 10A-10C illustrate an expandable bone implant, in accordance with a preferred embodiment of the invention;

Fig. 11 is an exploded view of a dental implant device in accordance with a preferred embodiment of the invention;

Figs. 12A-12C illustrate the use of an axially contracting tissue fastener, in accordance with a preferred embodiment of the invention;

Figs. 13A-13C illustrate a method of controlling the expansion of a spacer, in accordance with a preferred embodiment of the invention;

Figs. 14A and 14B illustrate a fin based locking mechanism in which one or more locking fins spring out from a bolt to engage a spacer, in accordance with a preferred embodiment of the invention;

Figs. 15A and 15B illustrate a locking mechanism similar to that of Figs. 14A-14B, utilizing plastic deformation, in accordance with a preferred embodiment of the invention;

Figs. 16A-16F illustrate a locking mechanism utilizing an expanding flange, in accordance with a preferred embodiment of the invention;

Figs. 17A-17C illustrate an alternative locking mechanism in which fins on a spacer engage a bolt inside of the spacer, in accordance with a preferred embodiment of the invention;

Figs. 18A-18D illustrate a locking mechanism in which fins on a bolt are extended when a pole element of the bolt is retracted, in accordance with a preferred embodiment of the invention;

Figs. 19A-19C illustrate a ring-based locking mechanism, in accordance with a preferred embodiment of the invention;

Fig. 20 illustrates a portion of a spacer, in which a plurality of banded areas indicate portions to be annealed, to assist in the expansion of the spacer, in accordance with a preferred embodiment of the invention; and

Figs. 21A and 21B illustrate spike designs for stress-release, in accordance with a preferred embodiment of the invention.

2. Delete the paragraph starting on page 19, line 20 and replace it with the following:

Figs. 1CA-1D show spacer 20 in an expanded configuration, Figs. 1CA and 1CB using a flat projection (side and axial) and Fig. 1D using a perspective view. When expanded, spikes 28 extend outwards and tube 22 is axially compressed. Non-spike segments 30 and end-cap(s) 34 preferably do not distort. As can be seen in the figures, a considerable expansion in diameter is achieved, for example a five fold expansion. In addition, a considerable axial contraction is

achieved, as evidenced by comparing the thickness of a spike 24 in Fig. 1CB (38) with Fig. 1A (28).

3. Delete the paragraph starting on page 32, line 11 and replace it with the following:

### **SPACER END CAP**

In some preferred embodiments of the invention, the end-cap protrudes from the spacer after it is expanded (as does end cap 108 in Fig. 2H). In some cases, the end cap may include a spike to engage bone tissue. Alternatively, the end cap may be formed to be within a plane defined by the end-most spikes. In one example, this is achieved by pre-folding the end-cap into the spacer. Alternatively, the end-cap may be folded into the spacer as part of the expansion process, for example (with reference to Fig. 2E), inverting end-cap 74 by pulling on member 72. Alternatively, the end-cap may be manufactured to elastically fold into the spacer. Alternatively, the deformation of the end spikes may fold the end-cap into the spacer. Additionally or alternatively, the end-cap may be retracted after the expansion of the spacer by pulling of a screw which engages the end-cap. Skipping ahead, Figs. 2OA-2OC illustrates a spacer in which the end-cap is formed to be inside the spacer, so that the expanding spikes reach all the way to the end of the spacer.

4. Delete the paragraph starting on page 46, line 6 and replace it with the following:

### **SQUARE SPACER EMBODIMENT**

Fig. 4A shows a flat projection of a spacer having a square cross-section when expanded, in an un-expanded configuration, in accordance with a preferred embodiment of the invention.

Figs. 4BA and 4BB shows a flat projection of the spacer of Fig. 4A, in an expanded configuration.

Fig. 4C shows a perspective projection of the spacer of Fig. 4A, in an expanded configuration. The above figures also include measurements for a preferred embodiment of the invention. For example, a length of 114 mm (un-expanded) and 23.9 mm (expanded), a diameter of 4 mm (un-expanded) and 14 mm (expanded) - each side, the material may be titanium, with a thickness of 0.5 mm. Alternatively or additionally, the material may comprise Nitinol (NiTi), Titanium, Surgical Stainless Steel, plastic, composite and/or various alloys, such as bio-inert metal alloys.

5. Delete the paragraph starting on page 46, line 29 and replace it with the following:

### **LORDOTIC SPACER**

Figs. 4DA and 4DB illustrates a variation of the spacer of Figs. 4A-4C, in which spikes

only extend in six transaxial directions and not eight, in accordance with a preferred embodiment of the invention.

6. Delete the paragraph starting on page 38, line 16 and replace it with the following:

In another example, the spike lengths are unequal on the two sides of the spacer, so when they push against the surrounding bone, the inner lumen is bent. Alternatively, the bending configuration is selected to create a desired contact and/or contact pressure between the spikes and the surrounding bone. Additionally or alternatively, the spike lengths and/or the slots are designed so that the spacer twists around its axis as it is expanded, for example, as shown in Figs. 5A-5C, where the spike slots are not parallel to the spacer axis.

7. Delete the paragraph starting on page 48, line 15 and replace it with the following:

Figs. 5A-5C illustrates a spacer 150 in which slits 152 are defined on the spacer in a spiral pattern. In this embodiment, spacer 150 may be expand by applying a rotational force to the spacer, rather than an axial force. In a preferred embodiment of the invention, one end of the spacer is modified to grip bone, to provide a suitable anchor for bone, for example as exemplified by a pair of extensions 154. In a preferred embodiment of the invention, extensions 154 fold out, for example as shown by dotted line 156, to radially grasp the bone prior to the expansion of the spacer. Preferably, the extensions are made of an elastic or super-elastic material which is maintained in an axial configuration until the spacer is inserted in place. Such anchoring may also be useful for other embodiments of the invention, described herein. However, in other preferred embodiments of the invention, no bone anchors are provided, as the spacer can expanded in place without anchoring.

8. Delete the paragraph starting on page 30, line 23 and replace it with the following:

#### SPACER DEFORMATION PROCESS

In a preferred embodiment of the invention, the spacer is expanded and collapsed using plastic deformation of the spacer material, whereby the tube is plastically deformed to form the expanded spacer. Alternatively, at least one of the expansion or collapsing uses elastic, super elastic or shape-memory properties of the material. In one example, the spacer is formed so that it is partially expanded and then elastically deformed to be completely collapsed prior to insertion. Thus, when the expansion starts, some or all of the spikes protrude from the spacer and increased axial force on the spacer will only urge the spikes further out and not in. It is noted that some

parts of the spacer may be designed to fold in, these parts may be elastically deformed away from their "interior position", prior to inserting the spacer. Fig. 6XIA-6XLB, described below, illustrate weakening portions of the spacer to control the shape of the extended spike.

**9.** Delete the paragraph starting on page 52, line 1 and replace it with the following:

#### **SELECTIVE WEAKENING**

Figs. 6XIA-6XLB illustrate (using a side view, with an axial portion of the spacer removed) examples of weakening of spacer material to aid in achieving some exemplary spikes profiles of those shown in Figs. 6A-6K. The weakening illustrated are etching and/or cutting of material in a direction perpendicular to the spacer surface. However, weakening may also be achieved using other means, for example, chemical or metallurgic treatment of by drilling small holes, for example in joints. Addition, the direction of the weakening may be at other orientations, for example along the surface of the spacer (as in Fig. 6XA) or at an angle thereto. Additionally or alternatively, the weakening and/or strengthening of the spacer is applied to provide a preferential distortion direction. Figs. 6XIA and 6XIB shows a weakening pattern which aids in achieving a symmetric spike. Figs. 6XJA and 6XJB shows a weakening pattern which aids in achieving an asymmetric spike. Figs. 6XKA-6XKC shows a weakening pattern which aids in achieving a flat top spike. Figs. 6XLA and 6XLB shows a weakening pattern which aids in achieving an arc shaped spike.

**10.** Delete the paragraph starting on page 58, line 10 and replace it with the following:

As an alternative embodiment (not shown) a single spike may span spikes 616 and 618. Referring back to Fig. 2K (multi-sub-spike spike example) a single spike may include two or more sub spikes, for example a sub-spike 616 and a sub-spike 618. When such a single spike partially extends, the two sub spikes engage the soft tissues. As the spike continues to extend (axial compression of the fastener) each of the sub spikes increases in radial extent and is brought closer together. Such behavior may be controlled by suitable weakening of the spikes, as described above, for example with reference to Figs. 6XIA and 6XIB, noting however, that if a spike is weakened by different amounts in different locations, the weaker location will typically fold first and then the strongest location, when axial compression is applied.

11. Delete the paragraph starting on page 52, line 22 and replace it with the following:

### PROTRUSIONS

Figs. 7A and 7B schematically illustrates protrusions on a spacer portion 400, in accordance with a preferred embodiment of the invention. The portion is show in a side view and in a perspective view. Portion 400 includes a spike 402 and a base portion (in some cases a ring segment) 410. In a preferred embodiment of the invention, a protrusion 404 and/or a protrusion 406 are provided to increase the stiffness of spike 402 and/or prevent its collapse under pressure. In the example of protrusion 404, spike 402 cannot fold to the right, because protrusion 404 is blocking the movement. In the example of protrusion 406, such movement is again blocked. Protrusion 406 may have an alternative or additional function of stiffening the spacer by filling in gaps between spike 402 and a neighboring (axially and/or radially offset) spike 408.

12. Delete the paragraph starting on page 31, line 10 and replace it with the following:

In another example, the spacer collapses by itself to the collapsed configuration, unless otherwise restrained, for example by a screw as described above and with reference to Figs. 2I and 2J. Additionally or alternatively, the spacer is maintained in shape using an interlock mechanism, preferably a ratchet-type mechanism. For example, in the embodiment of Figs. 8Ai and 8Aii (described below) two tabs may butt or overlap. If one tab includes a protrusion and the other tab includes a recess, when the tabs overlap, the protrusion engages the recess and a ratchet mechanism is formed. Additionally or alternatively, a dedicated ratchet mechanism may be formed by a barbed elongated internal member of the spacer which is connected at one end to the spacer and which engages a different part of the spacer using the barbed other end.

13. Delete the paragraph starting on page 53, line 5 and replace it with the following:

### AXIAL SHRINKAGE LIMITATION

Figs. 8Ai and 8Aii illustrates a spacer 420 in which axial shrinkage of the spacer is limited by the design of a tube portion 422 of the spacer, in accordance with a preferred embodiment of the invention. when spacer 420 is expanded, tube 422 axially contracts and spike 424 is extended. Additionally tube portions on either side of the spike advance towards each other. These portions are marked as a tab 428 and a tab 426 in the Figure. It is noted however, that only one such tab is required, since the other tube portion may be flush with the spike base or even back therefrom. When the two tabs meet, further axial contraction is impossible or is severely restricted. Further

contraction, if it were to occur, would require either that one of the tabs collapse or that one tab travels over the other tab. As noted above with respect to Fig. 6J, such a tab may be useful to guide the extension direction of a spike.

14. Delete the paragraph starting on page 54, line 12 and replace it with the following:

In the embodiments shown in Figs. 8Ai, 8Aii and 8B, the axial contraction restriction elements appear to be positioned instead of a spike. Although this is possible, it is not required. In alternative embodiments of the invention, at least some of the tabs and/or wave-folded tube portions may be radially located between spikes, for example, a radius including four spikes and four axial contraction restriction elements. Alternatively or additionally, a tab may be defined as part of the spike itself, for example as indicated by dotted lines 427 and 429 in Fig. 8Aii.

15. Delete the paragraph starting on page 55, line 9 and replace it with the following:

Alternatively or additionally, tool 454 may be bent by axial contraction thereof. As indicated above, the axial contraction may be uneven on the two sides of the spacer, for by reason of uneven distribution of tabs 426 (Fig. 8Aii). In one example, a regular axial contraction yields a straight tool tip. When the axial contraction is increased (e.g., and more spikes are expanded and/or more tabs abut), the tool bends in one direction, and when the contraction is further increased, the tool bends in another, possibly opposite, direction.